NDA 8-453/S-019

Glaxo Weilcome
5 Moore Drive
Research Triangle Park, NC 27709

OCT 02 2000

Attention: Robert Bohinski
Manager, Regulatory Affairs
Dear Mr. Bohinski:

Please refer to your supplemental new drug application dated July 17, 1997, received July 18, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ANECTINE® (succinyloholine chloride) Injection.

This supplemental new drug application provides final printed labeling for an updated carton labeling for ANECTINE® Injection which adds the revised warning statement**, "WARNING: Paralyzing Agent. Causes Respiratory Arrest"** and adds the revised statement of contents to include the total contents of each vial.

We have completed the review of this supplemental application and it is approved effective on the date of this letter. At the next printing or within 6 months, whichever occurs first, revise the statement of contents to **"200 mg/10 mL** (20 mg/mL)" and update the corporate information to reflect the merger between SmithKine Beecham and Glaxo Weilcome.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3l4.80 and 314.81.

If you have any questions, call Laura Governale, Pharm.D., Regulatory Project Manager, at (301) 827-7410.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

12 Multiple-Dose Vials 10 mL each

ANECTINE® Injection

(succinylcholine chloride)

NDC 0173-0071-95

200 mg/10 mL
(20 mg/mL)

A sterile non-pyrogenic solution for intravenous injection, made isotonic with sodium chloride, pH adjusted with hydrochloric acid and methylparaben 0.1% added as a preservative.

CAUTION: Federal law prohibits dispensing without prescription.

WARNING: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.

For indications, dosage, precautions, etc., see enclosed package insert.

FOR LOT NO. AND EXPIRATION DATE – SEE OTHER SIDE

411036
Rev. 7/97

12 Multiple-Dose Vials 10 mL each

ANECTINE® Injection
(succinylcholine chloride)

200 mg/10 mL (20 mg/mL)

Store under refrigeration 2° to 8°C (36° to 46°F).

GlaxoWellcome
Glaxo Wellcome Inc.
Research Triangle Park, NC 27709

12 Multiple-Dose Vials 10 mL each

ANECTINE® Injection
(succinylcholine chloride)

200 mg/10 mL (20 mg/mL)

Store under refrigeration 2° to 8°C (36° to 46°F).

GlaxoWellcome
Glaxo Wellcome Inc.
Research Triangle Park, NC 27709

©1996 Glaxo Wellcome Inc.

12 Multiple-Dose Vials 10 mL each

ANECTINE® Injection
(succinylcholine chloride)

NDC 0173-0071-95

200 mg/10 mL
(20 mg/mL)

A sterile non-pyrogenic solution for intravenous injection, made isotonic with sodium chloride, pH adjusted with hydrochloric acid and methylparaben 0.1% added as a preservative.

CAUTION: Federal law prohibits dispensing without prescription.

WARNING: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.

Store under refrigeration 2° to 8°C (36° to 46°F).